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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
NGUYEN, DAVE TRONG	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/005,338	DENEFLE ET AL.	
	Examiner	Art Unit	
	Dave T Nguyen	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-44* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Given an enormous number of claimed inventions which were purposely written within each of numerous claims as pending, the exact numbering of each of the claimed inventions required for the restriction will not be listed. However, the restriction requirement as indicated below clearly set forth an invention that can be chosen by applicant for examination.

Claims 1-6, 21-24, 34, 35, 44, are drawn to 122 distinct inventions, wherein each invention is drawn to one particularly named SEQ ID NO: as claimed among SEQ ID NOS: 1-4, and 9-126, vectors, host cells, compositions, and methods of producing the polypeptide by using the particularly named SEQ ID NO:, classifiable in Class 536, subclass 23.5; and Class 435, subclasses 325 and 320.1

Applicant is required to elect one particularly named SEQ ID NO, which corresponds to a particular named gene for examination, and should the invention be elected, the claims are only examined to the extent that the claims are drawn to the elected claimed invention.

Claims 7, 8, 16, are drawn to a plurality of distinct inventions, wherein each of the inventions is drawn to a ABCA5 probe or primer obtained from a particularly named SEQ ID NO: among SEQ ID NOS: 1-4, and 9-126, and wherein the elected probe or primer must be elected from claim 8 such that the elected probes or primers correspond only to the particularly named elected SEQ ID NO: chosen from SEQ ID NOS: 1-4, and 9-126, which in turns codes for a particular ABCA5. As such, the particularly named SEQ ID NO: and the corresponded probes or primers must be listed in the election. However, the elected probes and primers cannot be greater than 5 sequences. The plurality of these distinct inventions can be classifiable in class 435, subclass 6.

Applicant is required to elect one particularly named invention as required above, and should the invention be elected, the claims are only examined to the extent that the claims are drawn to the elected claimed invention.

Claims 7, 9, 16, are drawn to a plurality of distinct inventions, wherein each of the inventions is drawn to a ABCA6 probe or primer obtained from a particularly named SEQ ID NO: among SEQ ID NOS: 1-4, and 9-126, and wherein the elected probe or primer must be elected from claim 9 such that the elected probes or primers correspond only to the particularly named elected SEQ ID NO: chosen from SEQ ID NOS: 1-4, and 9-126, which in turns must code for a particular ABCA6. As such, the particularly named SEQ ID NO: and the corresponded probes or primers must be listed in the election. However, the elected probes and primers cannot be greater than 5 sequences. The plurality of these distinct inventions can be classifiable in class 435, subclass 6.

Applicant is required to elect one particularly named invention as required above, and should the invention be elected, the claims are only examined to the extent that the claims are drawn to the elected claimed invention.

Claims 7, 10, 16, are drawn to a plurality of distinct inventions, wherein each of the inventions is drawn to an ABCA9 probe or primer obtained from a particularly named SEQ ID NO: among SEQ ID NOS: 1-4, and 9-126, and wherein the elected probe or primer must be elected from claim 10 such that the elected probes or primers chosen must correspond only to the particularly named elected SEQ ID NO: chosen from SEQ ID NOS: 1-4, and 9-126, which in turns must code for a particular ABCA9. As such, the particularly named SEQ ID NO: and the corresponded probes or primers must be listed in the election. However, the elected probes and primers cannot be greater than 5 sequences. The plurality of these distinct inventions can be classifiable in class 435, subclass 6.

Applicant is required to elect one particularly named invention as required above, and should the invention be elected, the claims are only examined to the extent that the claims are drawn to the elected claimed invention.

Claims 7, 11, 16, are drawn to a plurality of distinct inventions, wherein each of the inventions is drawn to an ABCA10 probe or primer obtained from a particularly named SEQ ID NO: among SEQ ID NOS: 1-4, and 9-126, and wherein the elected probe or primer must be elected from claim 11 such that the elected probes or primers chosen must correspond only to the particularly named elected SEQ ID NO: chosen from SEQ ID NOS: 1-4, and 9-126, which in turns must code for a particular ABCA10. As such, the particularly named SEQ ID NO: and the corresponded probes or primers must be listed in the election. However, the elected probes and primers cannot be greater than 5 sequences. The plurality of these distinct inventions can be classifiable in class 435, subclass 6.

Applicant is required to elect one particularly named invention as required above, and should the invention be elected, the claims are only examined to the extent that the claims are drawn to the elected claimed invention.

Claims 12 and 14, are drawn to a plurality of distinct inventions, wherein each of the inventions is drawn to a method of employing two primers obtained from a particularly named SEQ ID NO: among SEQ ID NOS: 1-4, and 9-126, and wherein the elected probes or primers must correspond only to the particularly named elected SEQ ID NO: chosen from SEQ ID NOS: 1-4, and 9-126. As such, the particularly named SEQ ID NO: must be listed in the election. The plurality of these distinct inventions can be classifiable in class 435, subclass 6.

Should an invention be elected according to the immediately preceding paragraph, the elected claimed invention will be treated as a linking claim for one of the inventions chosen from claims 13 and 15 and listed below, which in turns must correspond to the elected claim invention chosen from claims 12 and 14. Note that the restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), as listed above. Upon the allowance of the linking claims, the restriction requirement as to the liked invention shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such (claim(s) depending from or including all the

limitations of the allowable lining claim(s) is/are presented in a continuation or divisional application, the claims or the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler,* 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Claims 13 and 15, drawn to a plurality of distinct inventions, wherein each of the invention is drawn to a set of two particularly named primers, which in turns must correspond to the elected invention of the linking claims, e.g., claims 12 and 14. The sets of two primer when elected must not exceed 5 sets of primers or probes.

Applicant is required to elect one particularly named invention as required above, and should the invention be elected, the claims are only examined to the extent that the claims are drawn to the elected claimed invention.

Claims 17-20, drawn to a plurality of distinct inventions, wherein each of the inventions is drawn to a method of employing a primer obtained from a particularly named SEQ ID NO:, which must correspond to an particular named ABC among SEQ ID NOS: 1-4, and 9-126, and wherein the elected probes or primers must correspond only to the particularly named elected SEQ ID NO: chosen from SEQ ID NOS: 1-4, and 9-126. The number of elected probes or primers can not exceed 10 sequences. The plurality of these distinct inventions can be classifiable in class 435, subclass 6.

Applicant is required to elect one particularly named invention as required above, and should the invention be elected, the claims are only examined to the extent that the claims are drawn to the elected claimed invention.

Claims 25-28, drawn to 4 distinct inventions of nucleic acids, where each of the invention is drawn to one particularly named SEQ ID NO chosen from SEQ ID NOS: 5-8.

Applicant is required to elect one particularly named invention as required above, and should the invention be elected, the claims are only examined to the extent that the claims are drawn to the elected claimed invention.

Claim 29, 39, drawn to 4 distinct inventions of polypeptides, where each of the invention is drawn to one particularly named SEQ ID NO chosen from SEQ ID NOS: 5-8.

Applicant is required to elect one particularly named invention as required above, and should the invention be elected, the claims are only examined to the extent that the claims are drawn to the elected claimed invention.

Claims 30-33, drawn to 4 distinct inventions of antibodies, where each of the invention is drawn to an antibody specific against a particularly named SEQ ID NO chosen from SEQ ID NOS: 5-8.

Applicant is required to elect one particularly named invention as required above, and should the invention be elected, the claims are only examined to the extent that the claims are drawn to the elected claimed invention.

Claims 36, 37, drawn to a plurality of distinct gene therapy methods, which each of the gene therapy invention is drawn to one particularly named SEQ ID NO: as claimed among SEQ ID NOS: 1-4, and 9-126. The elected invention chosen among the plurality of these gene therapy methods can be classifiable in class 514, subclass 44.

Applicant is required to elect one particularly named invention as required above, and should the invention be elected, the claims are only examined to the extent that the claims are drawn to the elected claimed invention.

Claim 38, drawn to a plurality of distinct protein therapy methods, which each of the therapy invention is drawn to one particularly named SEQ ID NO: as claimed among SEQ ID NOS: 5-8. The elected invention chosen among the plurality of these protein therapy methods can be classifiable in class 514, subclass 2.

Applicant is required to elect one particularly named invention as required above, and should the invention be elected, the claims are only examined to the extent that the claims are drawn to the elected claimed invention.

Claim 40-43, drawn to a plurality of distinct protein screening methods, which each of the screening invention is drawn to one particularly named SEQ ID NO: as claimed among SEQ ID NOS: 5-8. The elected invention chosen among the plurality of these protein screening methods can be classifiable in class 435, subclass 7.1.

Applicant is required to elect one particularly named invention as required above, and should the invention be elected, the claims are only examined to the extent that the claims are drawn to the elected claimed invention.

The inventions are distinct, each from the other because of the following reasons:

With respect to the nucleic acid claims, the polypeptide claims, the antibody claims, the inventions are directed to products that are district both physically and functionally, and are therefore patentably distinct; and are not required one for the other. For example, the polynucleotides are a fundamentally different type of molecule than the polypeptides, and the polynucleotides can be used in a

gene therapy method. The proteinsor polypeptides as claimed are structurally distinct from that of antibodies and can be used in treatment of patients having a disease in need of the polypeptides. Thus, these groups are directed to physically and functionally distinct elements, and are therefore patentably distinct; and are not required one for the other.

With respect to claims directed to multiple DNA, protein, or antibody sequences and/or ABC genes, each of the DNA sequences, protein sequences, or antibodies specific to a particular ligand, are drawn to a particularly named sequence with a particular string of nucleotide or amino acid residues. Each of sequences as claimed would code for and/or generate a particular function and/or effect. As such, a search of one particular named sequence would not necessarily overlap with that of another sequence. Furthermore, given a limited resource from the USPTO to conduct a prior art search for multiple sequences as claimed in this application, it would be unduly burdensome to the USPTO to examine and consider fully of the pending claims, which are dawn to an enormous number of sequences. As such and with respect to claims drawn to genes, proteins, or antibodies specific to a ligand, and/or method of use of each, the USPTO only can grant up to one particularly named gene, protein, antibody, or a specifically named SEQ ID NO: for examination. For claims drawn to probes and/or primers, the USPTO only can grant up to 5 specifically sets of two primers or 10 specifically named primers for examination.

Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to <u>different</u> methods, restriction is deemed to be proper because each of the methods of inventions as listed above constitutes patentably distinct inventions for the following reasons: A gene therapy method is not the same as a protein therapy method nor is it the same as a antibody screening assay nor is it the same as that of a protein screening assay. Each of the methods as claimed comprises materially distinct method steps and would generated a distinct function and effect.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, fall into different statutory classes of invention, and are separately classified and searched, restriction for examination purposes as indicated is proper, particularly in view of an undue burden to search and examine of all of the presently pending claims.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. ' 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. ' 1.48(b) and by the fee required under 37 C.F.R. ' 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner *Dave Nguyen* whose telephone number is **(703) 305-2024**.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *Deborah Reynolds*, may be reached at **(703) 305-4051.**

Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is **(703) 308-0196**.

Dave Nguyen
Primary Examiner
Art Unit: 1632

DAVE T. NGUYEN
PRIMARY EXAMINER